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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,645	10/03/2003	Corinna Sundermann	029310.52790US	7826

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/678,645

**Applicant(s)**

SUNDERMANN ET AL.

**Examiner**

Raymond J Henley III

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/6/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

**CLAIMS 1-24 ARE PRESENTED FOR EXAMINATION**

Applicants' Information Disclosure Statement filed January 6, 2004 has been received and entered into the application. As reflected by the attached, completed copy of form PTO/SB/08A (1 page), the cited references have been considered.

***Claim Objection***

Claims 16-21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 16 depends from claim 1 solely for the purpose of defining the compounds to be administered. This, however, fails to further limit the method of inhibiting nitric oxide synthase to which claim 1 is directed. Applicant is required to either cancel the claims, amend the claims to place them in proper dependent form, or rewrite the claims in independent form.

***Claim Rejection - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, last line, "with a physiologically acceptable acid" is unclear as to whether it is a requirement that the imidazo[1,2-a]pyridine compounds are administered with the acid or if the salt form of the compounds are formed with the acid.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

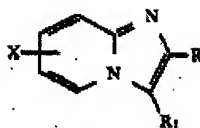
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***I*** Claims 1, 2, 5, 9, 16, 18, 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bender et al. (U.S. Patent No. 5,317,019, cited by the Examiner) who teaches a method of administering 2-(4-methoxyphenyl)-3-(4-pyridyl)-imidazo[1,2-a]-pyridine or a pharmaceutically acceptable salt thereof (col. 7, line 1 – col. 8, line 34 and col. 15, lines 4-6) to a mammal in order to inhibit interleukin-1 (IL-1) or tumor necrosis factor (TNF) production and thus treat any disease state or condition which is exacerbated or caused by excessive or unregulated IL-1 or TNF production (col. 18, lines 34-38 and col. 19, lines 52-58) including septic shock (col. 3, line 49), scar tissue formation, i.e., a wound (col. 3, lines 54-55), pain and other conditions associated with inflammation (col. 23, lines 1-2).

***II*** Claims 1-9, 16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Press (U.S. Patent No. 4,791,117, cited by the Examiner) who teach a method of administering to a mammal an effective amount of a 2- or 3-aryl substituted imidazo[1,2-a]pyridine of the formula I:

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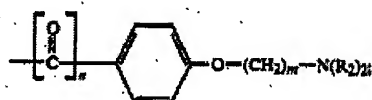
where

X may be hydrogen, halogen, hydroxy, alkoxy having 1-3 carbon atoms, benzyloxy, or C<sub>1</sub>-C<sub>6</sub> alkyl either singularly or in combination;

R may be H or Ar;

R<sub>1</sub> may be H, CH<sub>3</sub> or Ar;

Ar may be



R<sub>2</sub> may be a C<sub>1</sub>-C<sub>6</sub> alkyl;

n may be 0 or 1 when R is Ar; or

n may be 1 when R<sub>1</sub> is Ar; and

m may be 2-6, with the proviso that both R and R<sub>1</sub> cannot be Ar at the same time and at least one of R and R<sub>1</sub> is Ar.

for the preventative treatment of pain due to the compounds activity as a local anesthetic (col. 1, lines 35-44, col. 2, lines 5-41, col. 6, lines 23-50 and col. 16, claim 1 and compound Examples 1-14 at cols. 7-14).

The generic disclosure of pain by the patentee is deemed sufficient to place in the possession of the public, and thus anticipate, specific types of pain such as the claimed inflammatory pain.

**III** Claims 1-5, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Tenbrink (WO 96/25414, cited by Applicants) who teach a method of administering to a mammal an effective amount of a imidazo[1,2-a]pyridine compound encompassed by the present claims, i.e., a substituted hetero radical at applicants' R<sup>4</sup> (see the abstract, pages 1-10 and Chart L, beginning at page 65, compounds E-1 – E-3, E-6, E-7 and E-54) for the purpose of treating psychotic conditions (page 18, first full paragraph).

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**IV** Claims 1, 2, 5, 9, 16, 19, 21, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Tenbrink (WO 96/25414, cited by Applicants) who teach a method of administering to a mammal an effective amount of a imidazo[1,2-a]pyridine compound encompassed by the present claims, i.e., where applicants' R<sup>3</sup> and R<sup>4</sup> are unsubstituted or substituted aryl or heteroaryl radicals (see page 11, lines 4-20) for the purpose treating 5-lipoxygenase pathway/cyclooxygenase pathway/oxygenated polyunsaturated fatty acid mediated diseases/conditions (see the abstract and page 2, lines 33-35), including tissue trauma, i.e., a wound (page 38, lines 24-26), multiple sclerosis (page 38, lines 27-30), inflammatory diseases of the brain and spinal column (page 39, lines 20-24) and pain (page 65, line 34).

The generic teaching of inflammatory diseases of the brain and spinal column and of pain is deemed sufficient to place in the possession of the public, and thus anticipate, specific types of inflammatory diseases of the brain and spinal column such as the claimed meningitis or specific type of pain such as the claimed inflammatory pain.

#### ***Inherent Anticipation***

None of the above references teach inhibiting nitric oxide synthase (present claim 1). However, such activity is deemed inherent in the references' methods because the references teach the same drug being administered in the same manner and to the same host as presently claimed.

To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51

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U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J Henley III  
Primary Examiner  
Art Unit 1614

October 19, 2004